SECTION 2

SUMMARY

2.1 Introduction

The final regulations for the pharmaceutical manufacturing industry include effluent limitations guidelines and standards for the control of wastewater pollutants. This document presents the information and rationale supporting the final effluent limitations guidelines and standards. 2.2 presents the final subcategorization scheme, 2.3 describes the scope of the final regulations, and 2.4 through 2.9 summarize the effluent limitations guidelines and standards.

2.2 Subcategorization

EPA is maintaining the existing subcategorization scheme for this industry (40 CFR Part 439). These subcategories are summarized in the following table:

Subcategory Code (Subpart)	Subcategory
A	Fermentation Operations
B	Biological and Natural Extraction Operations
C	Chemical Synthesis Operations
D	Mixing, Compounding, or Formulating Operations
E	Pharmaceutical Research Operations

2.3 Scope of Regulations

These regulations apply to Subcategories A through D of the pharmaceutical manufacturing industry. Subcategory E (Research) operations are not revised by these regulations. Subcategory E operations at stand-alone facilities or at manufacturing facilities with Subcategory A, B, C, and/or D operations are covered by the existing BPT effluent limitations guidelines for Subcategory E.

Pharmaceutical manufacturers use many different raw materials and manufacturing processes to create a wide range of products with therapeutic value. Pharmaceutical products are produced by chemical synthesis, fermentation, extraction from naturally occurring plant or animal substances, or by refining a technical grade product.

The pharmaceutical products, processes, and activities covered by this regulation include:

- Biological products covered by the U.S. Department of Commerce, Bureau of the Census Standard Industrial Classification (SIC) Code No. 2836, with the exception of diagnostic substances. (Products covered by SIC Code No. 2836 were formerly covered under the 1977 SIC Code No. 2831.)

- Medicinal chemicals and botanical products covered by SIC Code No. 2833.

- Pharmaceutical products covered by SIC Code No. 2834.

- All fermentation, biological and natural extraction, chemical synthesis and formulation products considered to be pharmaceutically active ingredients by the Food and Drug Administration that are not covered by SIC Code Nos. 2833, 2834, or 2836.

- Multiple end-use products derived from pharmaceutical manufacturing operations (e.g., components of formulations, intermediates, or final products, provided that the primary use of the product is intended for pharmaceutical purposes).

- Products not covered by SIC Code Nos. 2833, 2834, and 2836 or other categorical limitations and standards if they are manufactured by a pharmaceutical manufacturer by processes that generate wastewaters that in turn closely correspond to those of pharmaceutical products. (An example of such a product is citric acid.)

- Cosmetic preparations covered by SIC Code No. 2844 that contain pharmaceutically active ingredients or ingredients intended for treatment of some skin condition. (This group of preparations does not include products such as lipsticks or perfumes that serve to enhance appearance or to provide a pleasing odor, but do not provide skin care. In general, this also excludes deodorants, manicure preparations, shaving preparations and non-medicated shampoos that do not function primarily as a skin treatment.)

Products or activities specifically excluded from the pharmaceutical manufacturing category are:

- Surgical and medical instruments and apparatus reported under SIC Code No. 3841.
- Orthopedic, prosthetic, and surgical appliances and supplies reported under SIC Code No. 3842.
- Dental equipment and supplies reported under SIC Code No. 3843.
- Medical laboratories services reported under SIC Code No. 8071.
- Dental laboratories services reported under SIC Code No. 8072.
- Outpatient care facility services reported under SIC Code No. 8081.
- Health and allied services reported under SIC Code No. 8091, and not classified elsewhere.
- Diagnostic devices other than those reported under SIC Code No. 3841.
- Animal feeds that include pharmaceutical active ingredients such as vitamins and antibiotics, where the major portion of the product is non-pharmaceutical, and the resulting process wastewater is not characteristic of process wastewater from the manufacture of pharmaceutical products.
- Foods and beverage products fortified with vitamins or other pharmaceutical active ingredients, where the major portion of the product is non-pharmaceutical, and the resulting process wastewater is not characteristic of process wastewater from the manufacture of pharmaceutical products.
- Pharmaceutical products and intermediates subject to the provisions of 40 CFR part 414, provided their manufacture results in less than 50 percent of the total flow of process wastewater that is regulated by 40 CFR part 414 at the facility.

In addition, facilities regulated by the organic chemicals, plastics and synthetic fibers (OCPSF) effluent limitations guidelines and standards (40 CFR 414) that manufacture pharmaceutical products and intermediates, will be subject to the OCPSF effluent guidelines and standards provided that the wastewater generated as a result of the manufacture of pharmaceutical products and intermediates is less than 50% of the total process wastewater flow at the facility.

2.4 Best Practicable Control Technology Currently Available (BPT)

EPA is revising the BPT effluent limitations guidelines for chemical oxygen demand (COD) for Subcategories A, B, C, and D. Table 2-1 presents these final limitations, which are based on the application of advanced biological treatment. The existing BPT effluent limitations guidelines for pH, BOD_5 and TSS are being maintained for all subcategories. The existing BPT effluent limitations guidelines for cyanide are being refined; the compliance monitoring requirements for these limitations have been clarified. Limitations on cyanide for B and D Subcategories are being withdrawn.

2.5 Best Conventional Pollutant Control Technology (BCT)

Existing BCT effluent limitations guidelines are not being revised.

2.6 Best Available Technology Economically Achievable (BAT)

EPA is revising the BAT effluent limitations guidelines for Subcategories A and C. For Subcategories A and C, EPA is adding BAT effluent limitations for ammonia as nitrogen (N), COD, and 30 priority and nonconventional organic pollutants. For Subcategories B and D, EPA is setting a BAT effluent limitation for COD that is equivalent to the BPT limitation. No additional BAT effluent limitations are being set for Subcategories B and D. However, EPA is withdrawing the current BAT effluent limitations for cyanide for Subcategories B and D. Tables 2-2 and 2-3 present these final effluent limitations guidelines, which are based on the following: end-of-pipe advanced biological treatment with nitrification for Subcategories A and C, and end-of-pipe advanced biological treatment for Subcategories B and D.

2.7 New Source Performance Standards (NSPS)

EPA is setting NSPS for priority and nonconventional pollutants for Subcategories A and C. The NSPS for Subcategories A and C include ammonia (as N) and 30 priority and nonconventional organic pollutants, based on advanced biological treatment with nitrification.

EPA is also revising the NSPS controlling discharges of BOD_5, COD, and TSS for Subcategories A, B, C, and D based on advanced biological treatment. EPA is withdrawing cyanide standards for Subcategories B and D. Final NSPS for Subcategories A and C are presented in Table 2-4. Final NSPS for Subcategories B and D are presented in Table 2-5.

2.8 Pretreatment Standards for Existing Sources (PSES)

EPA is revising PSES for priority and nonconventional pollutants for Subcategories A, B, C, and D. For Subcategories A and C, EPA is setting PSES for ammonia (as N) and 23 priority and nonconventional organic pollutants based on steam stripping. For Subcategories B and D, EPA is setting PSES for 5 priority and nonconventional organic pollutants based on steam stripping. Revised PSES for Subcategories A, B, C, and D are presented in Tables 2-6 and 2-7.

2.9 Pretreatment Standards for New Sources (PSNS)

EPA is revising PSNS for priority and nonconventional pollutants for Subcategories A, B, C, and D equal to PSES. Revised PSNS for Subcategories A, B, C, and D are presented in Tables 2-8 and 2-9.

Table 2-1

BPT Effluent Limitations for Subcategories A, B, C, and D

Subcategory	Pollutant or Pollutant Property	BPT Effluent Limitation for End-of-Pipe Monitoring Points	
		Maximum for any one day (mg/L)	Monthly Average (mg/L)
A: Fermentation Operations	COD	1,675	856
B: Biological and Natural Extraction Operations	COD	228	86
C: Chemical Synthesis Operations	COD	1,675	856
D: Mixing, Compounding, or Formulating Operations	COD	228	86

Table 2-2

BAT Effluent Limitations for Subcategory A - Fermentation Operations and Subcategory C - Chemical Synthesis Operations

Pollutant or Pollutant Property	BAT Effluent Limitations for End-of-Pipe Monitoring Points	
	Maximum for any 1 day mg/L	Monthly Average mg/L
Acetone	0.5	0.2
Acetonitrile	25.0	10.2
Ammonia as N	84.1	29.4
n-Amyl Acetate	1.3	0.5
Amyl Alcohol	10.0	4.1
Benzene	0.05	0.02
n-Butyl Acetate	1.3	0.5
Chemical Oxygen Demand (COD)	1,675	856
Chlorobenzene	0.15	0.06
Chloroform	0.02	0.01
o-Dichlorobenzene	0.15	0.06
1,2-Dichloroethane	0.4	0.1
Diethylamine	250.0	102.0
Dimethyl Sulfoxide	91.5	37.5
Ethanol	10.0	4.1
Ethyl Acetate	1.3	0.5
n-Heptane	0.05	0.02
n-Hexane	0.03	0.02
Isobutyraldehyde	1.2	0.5
Isopropanol	3.9	1.6
Isopropyl Acetate	1.3	0.5
Isopropyl Ether	8.4	2.6
Methanol	10.0	4.1
Methyl Cellosolve	100.0	40.6
Methylene Chloride	0.9	0.3
Methyl Formate	1.3	0.5
MIBK	0.5	0.2
Phenol	0.05	0.02
Tetrahydrofuran	8.4	2.6
Toluene	0.06	0.02
Triethylamine	250.0	102.0
Xylenes	0.03	0.01

Table 2-3

BAT Effluent Limitations for Subcategory B - Biological and Natural Extraction Operations and Subcategory D - Mixing, Compounding, or Formulating

Pollutant or Pollutant Property	BAT Effluent Limitations for End-of-Pipe Monitoring Points	
	Maximum for any 1 day mg/L	Monthly Average mg/L
Chemical Oxygen Demand (COD)	228	86

Table 2-4

NSPS for Subcategory A - Fermentation Operations and Subcategory C - Chemical Synthesis Operations

Pollutant or Pollutant Property	NSPS for End-of-Pipe Monitoring Points	
	Maximum for any 1 day mg/L	Monthly Average mg/L
Acetone	0.5	0.2
Acetonitrile	25.0	10.2
Ammonia as N	84.1	29.4
n-Amyl Acetate	1.3	0.5
Amyl Alcohol	10.0	4.1
Benzene	0.05	0.02
n-Butyl Acetate	1.3	0.5
Chlorobenzene	0.15	0.06
Chloroform	0.02	0.01
o-Dichlorobenzene	0.15	0.06
1,2-Dichloroethane	0.4	0.1
Diethylamine	250.0	102.0
Dimethyl Sulfoxide	91.5	37.5
Ethanol	10.0	4.1
Ethyl Acetate	1.3	0.5
n-Heptane	0.05	0.02
n-Hexane	0.03	0.02
Isobutyraldehyde	1.2	0.5
Isopropanol	3.9	1.6
Isopropyl Acetate	1.3	0.5
Isopropyl Ether	8.4	2.6
Methanol	10.0	4.1
Methyl Cellosolve	100.0	40.6
Methylene Chloride	0.9	0.3
Methyl Formate	1.3	0.5
MIBK	0.5	0.2
Phenol	0.05	0.02
Tetrahydrofuran	8.4	2.6
Toluene	0.06	0.02
Triethylamine	250.0	102.0
Xylenes	0.03	0.01
BOD_5	267	111
COD	1,675	856
TSS	472	166

Table 2-5

NSPS for Subcategory B - Biological and Natural Extraction Operations and Subcategory D - Mixing, Compounding, or Formulating

Pollutant or Pollutant Property	NSPS for End-of-Pipe Monitoring Points	
	Maximum for any 1 day mg/L	Monthly Average mg/L
BOD_5	35	18
COD	228	86
TSS	58	31

Table 2-6

PSES for Subcategory A - Fermentation Operations and Subcategory C - Chemical Synthesis Operations

Pollutant or Pollutant Property	PSES for End-of-Pipe Monitoring Points	
	Maximum for any 1 day mg/L	Monthly Average mg/L
Acetone	20.7	8.2
Ammonia as N	84.1	29.4
n-Amyl Acetate	20.7	8.2
Benzene	3.0	0.6
n-Butyl Acetate	20.7	8.2
Chlorobenzene	3.0	0.7
Chloroform	0.1	0.03
o-Dichlorobenzene	20.7	8.2
1,2-Dichloroethane	20.7	8.2
Diethylamine	255.0	100.0
Ethyl Acetate	20.7	8.2
n-Heptane	3.0	0.7
n-Hexane	3.0	0.7
Isobutyraldehyde	20.7	8.2
Isopropyl Acetate	20.7	8.2
Isopropyl Ether	20.7	8.2
Methyl Cellosolve	275.0	59.7
Methylene Chloride	3.0	0.7
Methyl Formate	20.7	8.2
MIBK	20.7	8.2
Tetrahydrofuran	9.2	3.4
Toluene	0.3	0.1
Triethylamine	255.0	100.0
Xylenes	3.0	0.7

Table 2-7

PSES for Subcategory B - Biological and Natural Extraction Operations and Subcategory D - Mixing, Compounding, or Formulating

Pollutant or Pollutant Property	PSES for End-of-Pipe Monitoring Points	
	Maximum for any 1 day mg/L	Monthly Average mg/L
Acetone	20.7	8.2
n-Amyl Acetate	20.7	8.2
Ethyl Acetate	20.7	8.2
Isopropyl Acetate	20.7	8.2
Methylene Chloride	3.0	0.7

Table 2-8

PSNS for Subcategory A - Fermentation Operations and Subcategory C - Chemical Synthesis Operations

Pollutant or Pollutant Property	PSNS for End-of-Pipe Monitoring Points	
	Maximum for any 1 day mg/L	Monthly Average mg/L
Acetone	20.7	8.2
Ammonia as N	84.1	29.4
n-Amyl Acetate	20.7	8.2
Benzene	3.0	0.6
n-Butyl Acetate	20.7	8.2
Chlorobenzene	3.0	0.7
Chloroform	0.1	0.03
o-Dichlorobenzene	20.7	8.2
1,2-Dichloroethane	20.7	8.2
Diethylamine	255.0	100.0
Ethyl Acetate	20.7	8.2
n-Heptane	3.0	0.7
n-Hexane	3.0	0.7
Isobutyraldehyde	20.7	8.2
Isopropyl Acetate	20.7	8.2
Isopropyl Ether	20.7	8.2
Methyl Cellosolve	275.0	59.7
Methylene Chloride	3.0	0.7
Methyl Formate	20.7	8.2
MIBK	20.7	8.2
Tetrahydrofuran	9.2	3.4
Toluene	0.3	0.1
Triethylamine	255.0	100.0
Xylenes	3.0	0.7

Table 2-9

PSNS for Subcategory B - Biological and Natural Extraction Operations and Subcategory D - Mixing, Compounding, or Formulating Operations

Pollutant or Pollutant Property	PSNS for End-of-Pipe Monitoring Points	
	Maximum for any 1 day mg/L	Monthly Average mg/L
Acetone	20.7	8.2
n-Amyl Acetate	20.7	8.2
Ethyl Acetate	20.7	8.2
Isopropyl Acetate	20.7	8.2
Methylene Chloride	3.0	0.7